State of California—Health and Human Services Agency
California Department of Public Health

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TO: Vaccines for Children (VFC) Providers

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SUBJECT: VFC 2012-13 Seasonal Influenza Vaccine Information

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SUMMARY

The 2012 recommendations of the federal Advisory Committee on Immunization Practices (ACIP) on the *Prevention and Control of Influenza with Vaccines* is posted at http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6132a3.htm?s_cid=mm6132a3_w. Routine annual influenza immunization continues to be recommended for all children and persons 6 months and older, including all adults. VFC vaccine cannot be given to persons older than 18 years of age. Children younger than 9 years of age who are not previously immunized need 2 doses of influenza vaccine for optimal protection. Providers should offer influenza immunization as soon as vaccine is available and throughout the influenza season. On June 18, 2012, providers were sent instructions for confirming their 2012-13 VFC allocations through the Seasonal Influenza On-line Order Confirmation System at www.eziz.org. All confirmed orders have been approved.

2012-13 INFLUENZA VACCINE COMPOSITION

The 2012-13 trivalent vaccine virus strains in this year's influenza vaccine, representative of viruses that are anticipated to circulate in the U.S. during the 2012-13 influenza season, include H3N2 and B strains that were not in the 2011-12 seasonal influenza vaccine:

- A/California/7/2009 (H1N1)-like – derived from a 2009 pandemic (H1N1) influenza virus)
- A/Victoria/361/2011 (H3N2)-like – new for this season
- B/Wisconsin/1/2010-like (Yamagata lineage) – new for this season.

Persons that received influenza vaccine in previous seasons are recommended to be immunized with 2012-13 influenza vaccine for optimal protection against influenza.

VFC INFLUENZA VACCINE FORMULATIONS

The Vaccines for Children (VFC) Program will make available a variety of licensed influenza vaccines for the 2012-13 influenza season, including:

VFC-eligible Children ages 6 through 35 months

- Fluzone® PF Pediatric (sanofi pasteur), No preservative. Available as 0.25mL pre-filled syringes. Intramuscular injection.

VFC-eligible Children and Youth through age 18 years

- Fluzone® (sanofi pasteur), preservative-containing (children and adolescents aged 3 through 18 years). Multi-dose vial. Intramuscular injection.
- FluMist® (MedImmune), preservative-free, live attenuated intranasal vaccine (only healthy, non-pregnant children and adolescents aged 2 through 18 years of age). 0.2 mL single-use sprayer. Intranasal administration.
- Fluarix® (GlaxoSmithKline), no preservative (for use in children and youth ages 3 through 18 years and pregnant women who are VFC-eligible). Available as 0.5 mL single-dose pre-filled syringes. Intramuscular injection.

According to California law, pregnant women or children younger than 3 years old may only receive vaccine doses that contain no more than trace levels of mercury [Health and Safety (H&S) Code Section 124172, Chapter 837, Statutes of 2004 (AB 2943, Pavley)]**. All multi-dose vials of influenza vaccine currently exceed the legal limit of mercury content and should not be used in these groups.** Preservative-free influenza VFC vaccine formulations should be used for administration to VFC-eligible children younger than 3 years of age and pregnant teens younger than 19 years of age.

ELIGIBILITY FOR VFC-SUPPLIED SEASONAL INFLUENZA VACCINE

VFC-supplied seasonal influenza vaccine may be used for all VFC-eligible children in the ACIP recommended groups using appropriate indications for the specific vaccine:

Eligible Groups for Inactivated Seasonal Influenza Vaccine

- All children aged 6 months through 18 years.

Eligible Groups for Live Attenuated Seasonal Influenza Vaccine (LAIV)

- All healthy, non-pregnant children and adolescents (those who do not have an underlying medical condition that predisposes them to severe influenza) aged 2 years through 18 years.

DOSAGE AND ADMINISTRATION
Inactivated Seasonal Influenza Vaccine

- For children 6-35 months of age, one dose is 0.25 mL
- For children ≥36 months of age, one dose is 0.50 mL

The vaccine syringe or vial should be shaken well before administration. Vaccine should be inspected visually for particulate matter and discoloration prior to administration. If either of these conditions exists, the vaccine should not be administered.

Inactivated influenza vaccine should be administered intramuscularly in the anterolateral aspect of the thigh for infants and young children. Adults and older children should be vaccinated in the deltoid muscle.

LAIV
LAIV is only administered **intranasally**. The vaccine is supplied in pre-filled, single-use sprayers containing 0.2 mL of vaccine. One half of the sprayer's contents (0.1 mL) should be sprayed into each nostril while the patient is in an upright position. Do not repeat a dose if the patient sneezes after administration of the dose.

Number of doses
Children 9 years and older are recommended to receive 1 dose of 2012-13 seasonal influenza vaccine.

Children 6 months through 8 years of age are recommended to receive 2 doses of 2012-13 seasonal influenza vaccine (administered a minimum of 4 weeks apart). However, some children in this age group may need only 1 dose of 2012-2013 seasonal influenza, depending on the number of seasonal influenza doses and monovalent 2009 H1N1 doses received in previous seasons. The ACIP recommendations on the Prevention and Control of Influenza with Vaccines for the 2012-2013 Influenza Season include two approaches for determining the number of doses required for children aged 6 through 8 years of age.

The first approach is harmonized with the American Academy of Pediatrics and addresses situations in which ascertaining vaccination history before the 2010-2011 season is difficult. See Figure 1 of CDC's Prevention and Control of Influenza with Vaccines.

The second approach may be used in situations or settings where adequate vaccination history prior to the 2010-2011 season is available. See the full text of CDC's *Prevention and Control of Influenza with Vaccines.*

Egg Allergy
A history of severe allergic reaction or anaphylaxis to influenza vaccine remains a contraindication to influenza immunization; however, this is not equivalent to history of egg allergy. Influenza immunization has often occurred safely in persons who reported a history of egg allergy. The quantity of egg protein (ovalbumin) in vaccine is low and has been tolerated without serious reactions in studies that reported ovalbumin concentration. Please see ACIP recommendations for further information.

Vaccine Management and Training
Your office or clinic may receive a variety of influenza vaccine formulations, including privately purchased doses for non-VFC eligible patients. The attached "Flu Vial Identification Chart" may

help you identify all available influenza vaccines, including formulations that are not provided by the VFC program:

- *intradermal* vaccine for persons aged 18 through 64 years
- *high-dose*, intramuscular influenza vaccine for persons aged 65 years and older.

It is extremely important that staff review **all** (VFC, non-VFC) influenza vaccine products that you will be administering in your facility this year, including their dosages, age indications, and administration techniques. We strongly encourage yearly competency review of all staff administering any vaccine formulation, including influenza.

Any inactivated influenza products that are exposed to freezing temperatures cannot be used. Aim for a temperature of 40°F in all of your refrigerators that store vaccines. Clinic staff involved in ordering, managing vaccine inventory, and administering vaccines are strongly encouraged to complete VFC's EZIZ on-line Vaccine Administration and Storage and Handling and Temperature Monitoring lessons, accessible at www.eziz.org.

VACCINE INFORMATION STATEMENTS (VISs)

The appropriate influenza Vaccine Information Statement (VIS) for Inactivated or Live, Attenuated Influenza Vaccine (LAIV) for 2012-2013 must be provided to a parent or guardian before the child receives each dose of influenza vaccine. Each time a VIS is provided the following information must be included in each patient's permanent medical record:

(1) Edition date of the current Vaccine Information Statement that was provided
(2) Date that the VIS was provided.

Copies of the 2012-13 Influenza VISs are enclosed. Please discard any remaining copies of the Influenza VIS from prior seasons.

ORDERING INSTRUCTIONS

VFC's On-line Order Confirmation System was open for the submission of requests for 2012-13 seasonal flu vaccine from June 18 through July 18, 2012. All orders confirmed by the deadline have been reviewed and approved. (The June 2012 provider notice and order confirmation instructions are available at www.eziz.org.) Confirmation of the total influenza vaccine doses, by brand, in each order was sent electronically to the clinic's provider of record by July 31, 2012.

Supplemental Flu Orders

Providers who did not confirm orders by the July deadline or who wish to order additional doses may submit a supplemental vaccine request in late autumn, at which time VFC will provide additional information.

Timing of Vaccine Supply

It is anticipated that up to 50% of expected doses of VFC influenza vaccine will become available by late September, with the remaining balance available by late October.

Order Fulfillment and Shipments

All orders confirmed by the date of this letter will begin to be processed as soon as doses become available. Orders will be filled in the order received. Orders will typically be shipped in increments, as the timing and volume of deliveries to the distributor vary for each formulation of influenza vaccine. Order fulfillment information will be posted and updated as necessary on www.eziz.org in the "Order Status" section.

STORAGE AND HANDLING OF INFLUENZA VACCINES

Prior to receiving your influenza vaccine request, please ensure that:

- You have sufficient space in your vaccine refrigerator(s) to store your influenza vaccine along with all of your other vaccines.
- All supplies of VFC seasonal influenza vaccine from 2011-12 or earlier are removed from your refrigerator and returned to McKesson Specialty Inc. See page 6 for instructions on returning expired vaccine.

Once your vaccines arrive:
All influenza vaccine formulations, including LAIV, will be shipped to your practice directly from McKesson Specialty Inc., in insulated containers maintaining a constant temperature between 35° to 46°F (2° to 8°C). **Immediately upon receipt**:

- Check the temperature monitors included in your shipment. If the monitors indicate the vaccine has been exposed to suboptimal temperatures during transit:
    - Contact the VFC Program **immediately**
    - Instruct clinic staff to label the vaccines "Do not use"
    - Refrigerate the vaccines until you have received further instructions from the VFC program.
- Verify that the number and type of vaccine doses received matches the information **both** in your shipment's packing slip and in the e-mailed order confirmation. Contact the VFC Program **immediately** to report any discrepancy in your order.
- Refrigerate vaccines at a temperature range of 35°F to 46°F (2°C to 8°C), with a preferred temperature of 40°F. Do not freeze or expose vaccines to freezing temperatures.
- Keep vaccines in their original packaging until they are ready to be administered. (DO NOT take vaccine vials or syringes out of their packaging.)

BILLING NOTES

Medi-Cal:

To bill Medi-Cal for administration of VFC-supplied influenza vaccines, use the appropriate CPT-4 code followed by the "-SL" modifier. Providers will only be reimbursed for the administration fee when using VFC vaccines.

For specific information and details on Medi-Cal billing, please refer to the Medi-Cal provider manual on VFC. Providers with questions on Medi-Cal billing policies and procedures and Provider manual information may call the Telephone Service Center (TSC) at 1-800-541-5555.

Child Health and Disability Prevention Program (CHDP):

The CHDP program will reimburse for seasonal influenza vaccine and its administration.

- If seasonal influenza vaccine is provided by the VFC Program use code "53," for administration fee only.
- If seasonal influenza vaccine is purchased because the vaccine is not available through VFC, use code "54" for children 36 months through 20 years, 11 months and code "80" (preservative free) for children 6 months through 35 months.
- If Live Attenuated Influenza Vaccine (LAIV), intranasally administered is provided by the VFC Program use code "71." Code 71 is payable for ages two years through 18 years, 11 months, administration fee only.

PROMOTING FLU VACCINATION IN YOUR OFFICE
A number of influenza promotion materials are available for you, your staff, and your patients. We encourage you to post them around your office. To see what's available this year, visit the flu resources page on EZIZ.org: http://eziz.org/resources/flu-promo-materials/. A sample packet of available materials will be included in your clinic's first vaccine shipment.

RETURN OF UNUSED INFLUENZA VACCINE
All VFC Providers must return all expired or spoiled seasonal influenza vaccine (including vials, syringes, and nasal sprayer packages) received from VFC to the program's national vaccine distributor, McKesson Specialty Inc.

To return vaccine, please submit a completed VFC Return and Transfer Form either:
- Electronically using MYVFCVaccines.
- By faxing to 877-FAXX-VFC (877-329-9832).

When submitting the Return and Transfer Form, you may request return shipping labels, which should arrive at your office within 10 business days. Please enclose a copy of the completed Return and Transfer Form in the return shipment package. Please keep the returned doses in their original packaging. Please ship in a container in which you receive your typical vaccine shipments. Clearly label the outside of the shipping container "Non-viable vaccine enclosed."

LAIV Replacement Program
LAIV has a briefer expiration date, with some lots expiring as early as December 2012. Providers may request replacement of eligible LAIV up to 15 days prior to the expiration date printed on the sprayer label. Details for this year's LAIV replacement program will be posted on www.eziz.org once available.

QUESTIONS?
If you have any questions, please call your VFC Field Representative, the VFC Program at 877-243-8832 (877-2GET-VFC), or visit www.eziz.org.

Encl: Identifying Influenza Vaccine Chart
Live, Intranasal Influenza Vaccine 2012-13 (7/2/12)
Inactivated Influenza Vaccine Statement 2012-13 (7/2/12)

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